

MAR 24 2000

Biovail Laboratories Incorporated
Attention: Mr. John Dubeck
1001 G Street, N.W.
Washington, D.C. 20001

Dear Mr. Dubeck:

Please refer to your supplemental new drug application dated November 16, 1999, received November 17, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tiazac (diltiazem hydrochloride) Capsules.

We acknowledge receipt of your submission dated January 4, 2000.

This supplement provides for draft labeling revised under **Dosage and Administration** to include the following:

Sprinkling the Capsule Contents on Food

Tiazac Extended Release Capsules may also be administered by carefully opening the capsules and sprinkling the capsule contents on a spoonful of applesauce. The applesauce should be swallowed immediately without chewing, and followed with a glass of cool water to ensure complete swallowing of the capsule contents. The applesauce should not be hot and it should be soft enough to be swallowed without chewing. Any capsule contents/applesauce mixture should be used immediately and not stored for future use. Subdividing the contents of a Tiazac Extended Release Capsule is not recommended.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted November 17, 1999).